REMARKS

I. Status of the Claims

Claims 1-85, 87-92 and 100 are pending and have been made the subject of a restriction requirement.

II. Response to the Restriction Requirement

The Office alleges that the claims lack unity of invention, and has required restriction between Groups I-XVIII, characterized by the Examiner as follows:

Group I. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 6-membered ring; V is alkyl or absent; W is O; and Ar_1 is an optionally fused phenyl ring, according to Claims 1-78.

Group II. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 6-membered ring; V is alkyl or absent; W is O; and Ar_1 is a pyrazole ring, according to Claims 1-78.

Group III. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 5-membered ring; V is alkyl or absent; W is O; and Ar_1 is an optionally fused phenyl ring, according to Claims 1-78.

Group IV. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 5-membered ring; V is alkyl or absent; W is O; and Ar_1 is a pyrazole ring, according to Claims 1-78.

Group V. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 6-membered ring; V is alkyl or absent; W is NH; and Ar_1 is an optionally fused phenyl ring, according to Claims 1-78.

Group VI. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 6-membered ring; V is alkyl or absent; W is NH; and Ar_1 is a pyrazole ring, according to Claims 1-78.

Group VII. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 5-membered ring; V is alkyl or absent; W is NH; and Ar_1 is an optionally fused phenyl ring, according to Claims 1-78.

Group VIII. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 5-membered ring; V is alkyl or absent; W is NH; and Ar_1 is a pyrazole ring, according to Claims 1-78.

Group IX. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 6-membered ring; V is alkyl or absent; W is absent; and Ar_1 is an optionally fused phenyl ring, according to Claims 1-78.

Group X. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 6-membered ring; V is alkyl or absent; W is absent; and Ar_1 is a pyrazole ring, according to Claims 1-78.

Group XI. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 5-membered ring; V is alkyl or absent; W is absent; and Ar_1 is an optionally fused phenyl ring, according to Claims 1-78.

Group XII. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 5-membered ring; V is alkyl or absent; W is absent; and Ar_1 is a pyrazole ring, according to Claims 1-78.

Group XIII. The compound or composition of the formula Ia, not previously described in any of the above groups, according to claims 1-78.

Group XIV. A method for prophylaxis or treatment of a metabolic disorder by administering a compound according to one ofthe above groups, according to Claims 79-81.

Group XV. A method for controlling or decreasing weight gain, according to Claim 82.

Group XVI. A method of modulating a RUP3 receptor, according to claim 83.

Group XVII. A method of modulating a RUP3 receptor, according to claim 84, 85, 87- 92.

Group XVIII. A method of producing a pharmaceutical composition, according to claim 100

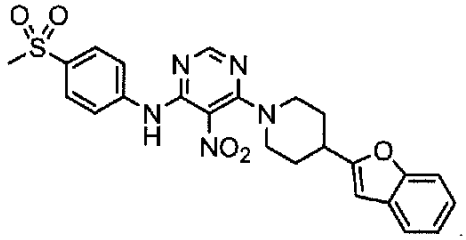
The applicants **elect Group V, but respectfully traverse the restriction requirement.** The applicants respectfully submit that the restriction requirement made is improper, at least because: (A) the Office has not demonstrated that the claims lack unity of invention; (B) the groups from among which election is being required are arbitrary and improper; (C) no undue burden of searching the entire scope of the invention has been established; (D) the restriction requirement is incomplete; (E) the restriction requirement is unclear; and (F) at least some of claims 1-78 are linking claims linking Groups I-XIII.

The Office Action also states:

This application contains claims directed to the following patentably distinct species the compounds of Claims 73-76. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic.

The applicants elect [6-(4-benzofuran-2-yl-piperidin-1-yl)-5-nitro-pyrimidin-4-yl]-(4-methanesulfonyl-phenyl)-amine (identified in the specification as compound B125), i.e. the compound having the following structure:



The following claims are believed to be readable on the above-identified compound: 1, 2, 3, 11, 14, 16, 20, 32, 40, 41, 42, 43, 44, 57, 58, 59, 70 and 74. Claim 78 is believed to be readable on a pharamaceutical composition of the above compound. Claims 79-85, 87-92 and 100 are readable on methods using the above compound.

This election is also made **with traverse**. In accordance with the decision in *Caterpillar Tractor Co. v. Com'r Pat. & Trademarks*, 650 F.Supp. 218 (E.D. Va. 1986), the Office is bound by the provisions of the P.C.T. with regard to the scope examination of national stage P.C.T. applications. The P.C.T. and P.C.T. rules provide that an applicant is entitled to examination of all those "inventions so linked as to form a single general inventive concept." *See* P.C.T. Rule 13.1. Nothing in the P.C.T. or the P.C.T. rules permits the Office to limit examination to a single species if no generic claim is held to be allowable. The applicants are entitled to examination of the entire subject matter of the application to the extent that the requirement of unity of invention is met.

(A) Unity of Invention

The applicants respectfully point out that the issue of unity of invention among the claims of the present application has already been passed upon in the international phase, where the requirement of unity of invention was found to be satisfied. The restriction requirement is based upon the Examiner's assertion that the claims lack unity of invention. The Examiner's assertion that the claims lack unity of invention is in direct conflict with the position already taken by the International Searching Authority on the issue of invention. The present application was filed as PCT Application PCT/US2004/001267 and preliminarily examined in the international phase by the European Patent Office (EPO). An International Preliminary Report on Patentability (IPRP) was issued by the EPO on July 15, 2005. Box IV of the IPRP was *not* checked, clearly indicating that the requirement of unity of invention was considered to be satisfied by the International Searching Authority. Moreover, the International Searching Authority performed a *complete search* with respect to the claimed invention, and did not indicate that the search was difficult or unduly burdensome to perform.

Contrary to the findings of the International Searching Authority, the Examiner alleges that unity is lacking because the inventions of Groups I-XVIII are allegedly not so linked as to form a single general inventive concept under PCT Rule 13. It is unclear how this conclusion has been drawn because the Examiner provides no analysis of whether these groups share the same or corresponding special technical features. No prior art has been cited to demonstrate that the common features of the compounds of formula Ia do not represent a contribution over the prior art. As discussed in greater detail herein, the compounds of formula Ia as defined in claim 1, do in fact, share substantial common structural features which are sufficient to establish unity of invention of the pending claims under P.C.T. Rule 13.

(1) The Applicable Legal Standard for Unity of Invention

"Unity of invention (not restriction) practice is applicable in ... national stage applications submitted under 35 U.S.C. 371." MPEP 1893.03(d). Unity of invention must be determined under the provisions of the P.C.T. in a national stage application filed under 35

U.S.C. § 371. *Caterpillar Tractor Co. v. Com'r Pat. & Trademarks*, 650 F.Supp. 218 (E.D. Va. 1986). Therefore, the legal standards applicable to making a restriction requirement in an application filed under 35 U.S.C. § 371 are those set forth for determining unity of invention under the P.C.T. as given in the P.C.T. itself and the P.C.T. rules (specifically Rule 13).

The standard for unity of invention under the P.C.T. as set forth in P.C.T. Rule 13, states:

> "the requirement of unity of invention ... shall be fulfilled ... when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art"

P.C.T. Rule 13.2. Unity of invention is satisfied when there is a special technical feature linking the claims. The presence of a special technical feature linking the claims thus defines the unity of invention standard.

Authoritative guidelines for determining whether there is unity of invention in specific situations are provided in the Annex B to the Administrative Instructions under the P.C.T. (the "Administrative Instructions") and also in Chapter 10 of the P.C.T. International Search and Preliminary Examination Guidelines (the "Preliminary Examination Guidelines"). Particular standards set forth in these guidelines that are relevant to unity of invention in the present application are discussed in greater detail below.

First, where there is unity of invention within and among independent claims, there is also unity of invention among dependent claims. The Administrative Instructions explain that unity of invention should be considered first in relation to the independent claims. Then, "[i]f the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims" Administrative Instructions under the P.C.T. Annex B, para. (c)(i).

Second, there is unity of invention as between a claims to a product, and claims to methods of making and using the product. The Administrative Instructions explain that the standard for unity of invention under Rule 13.2 should be construed as permitting "in addition to

an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product." Administrative Instructions under the P.C.T. Annex B, para. (c)(i).

Third, the Administrative Instructions establish that when a series of chemical compounds is defined in a claim using so-called "Markush practice" enumerating alternative elements, "[t]he fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention." Administrative Instructions under the P.C.T. Annex B, para. (f)(iv). Unity of invention is satisfied when a significant structural element is shared by all of the alternatives. The significant structural element may be a single component or a combination of individual structural elements linked together. Administrative Instructions under the P.C.T. Annex B, para. (f).

(2) The Common Features of the Compounds of Formula (Ia) Constitute Special Technical Features Linking the Claims

The sole rationale provided by the Examiner supporting the finding lack of unity of invention is as follows:

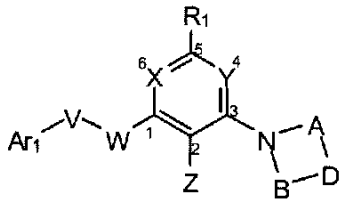
> In the instant case, Groups I-XIII are directed to structurally dissimilar compounds such that the variable core created by varying the definitions of the Formula do not belong to a recognized class of chemical compounds in the art, and references that exist in anticipating one invention would not render obvious the others. For example, 1-[6-(4-Imidazol-1-yl-phenoxy)-5-nitro-pyrimidin-4-yl]-piperidine-4-carboxylic acid ethyl ester is different from 1-{4-[2-Nitro-3-(4-propyl-piperidin-1-yl)-phenoxy]-phenyl}-ethanone. Thus, separate searches in the literature would be required. Each group's compounds are made and used independently of each other and could support separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structures as functional equivalents of each other. The mere fact that there is a single similarity is not in itself a significant reason to render the whole embodiment obvious. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Therefore the feature linking the claims does not constitute

a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the art.

See paragraph 2 of the Office Action.

Referring to the legal standards described above, it is apparent that the reasons given by the Examiner for insisting upon restriction fail to address the proper factor to be considered in assessing unity of invention, namely the presence or otherwise of a special technical feature. Instead the Examiner focuses on issues (such as patent classification) that are entirely irrelevant to the issue of unity of invention. The applicants respectfully point out that claims can have unity of invention even though they might encompass a diversity of compounds and might vary in classification so these factors are irrelevant to the issue of unity of invention. Further, inventions need not be obvious variants in order to share unity of invention. Rather, the sole requirement for unity of invention is that the claims be directed to the same general inventive concept as defined by the presence of a special technical feature. This one relevant factor, however, does not appear to have been considered in making the restriction requirement.

As the International Searching Authority found, the claims of the present application meet the requirement of unity of invention because the compounds of Formula Ia are a common feature of the claims. The compounds according to Formula Ia (Figure 1) themselves have numerous common features.



(Ia)

Figure 1. Common Structural Features of the Compounds According to Formula Ia

Theses common features include, for example:

- A six membered aromatic core ring having carbon atoms at at least three adjacent positions (positions 1,2, and 3) and at at least a fourth position not adjacent to the first

three (position 5). (This numbering of the positions is arbitrary and is as show in Figure 1).

- An aromatic ring optionally linked by a linking group as a substituent at position 1.
- A substituent at position 2.
- A cyclic amine as a substituent at position 3.

As the International Searching Authority apparently appreciated when it performed the international preliminary examination, the above combination of features constitutes a significant common structural element sufficient to satisfy the unity of invention requirement. Unity of invention is satisfied when a significant structural element is shared by all of the alternatives. The significant structural element required to satisfy unity of invention may be a single component or a combination of individual structural elements linked together. Administrative Instructions under the P.C.T. Annex B, para. (f).

The Office has not established that the common features of the compounds according to Formula (A) fail to constitute a special technical feature linking the claims at least because the Office has not cited any prior art which would prevent the compounds of formula Ia from constituting a special technical feature to satisfy the requirement of unity of invention.

The different definitions of the ring atoms X and Y and substituents R_1 in Groups I-XIII do not establish lack of unity of invention. Although X and Y may be selected such that different core rings may be formed, the resulting core rings would all be 6 membered aromatic rings of very similar geometry, resulting in a geometrically similar disposition of the substituents at positions 1, 2, 3, and 5 (using the numbering convention referred to above). Those substituents themselves have common features as required by the definitions in claim 1. Further, any differences in the definitions of X and Y provide no excuse for insisting upon restriction among Groups I-XII because these Groups all have common definitions of X and Y (as N).

The court in *In re Harnisch,* 631 F.2d 716 (CCPA 1980) applied the standard of unity of invention in relation to the propriety of a restriction requirement in a domestic application. Unity

of invention was held to exist where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility. MPEP 803.02. The claims to the compounds claim 1 meet the unity of invention standard as defined in *Harnisch* , at least because:

(1) the compounds share the *common utility* of modulating the activity of the RUP3 receptor;

(2) the compounds *share a substantial structural feature* as defined above;

(3) the structure of the compounds as defined in formula I will be understood to be *essential to the utility* of the compounds because it is well known that biological activity of pharmaceutical compounds is a result of the molecular interaction between the compounds and the biological macromolecules that are the effectors of the biological response, and hence dependent on the molecular structure of the compounds.

No case has been made that the International Searching Authority was mistaken when it determined that the claims meet the unity of requirement. The Office has not shown that the common features of the compounds according to formula Ia fail to constitute a special technical feature linking the claims. Accordingly, the claims have not been shown to lack unity of invention, and the restriction requirement is therefore manifestly improper.

(3) The Use Claims 79-85, 87-92 and 100 Share Unity of Invention with Compound Claims 1-78 Based upon the Common Features of the Compounds According to Formula (Ia) as a Special Technical Feature and the Dependency of these Claims

The restriction requirement is also inconsistent with the standards for unity of invention under the P.C.T. and manifestly improper insofar as restriction is being required among claims to compounds and compositions (in Groups I-XIII) and methods of using these compounds (in Groups XIV-XVIII). The impropriety of the restriction requirement is apparent at least because the novel compounds constitute a special technical feature linking the claims to the compounds with the claims to methods for their use.

The impropriety of the division of the method of use claims 79-85, 87-92 and 100 from the compound claims of claims 1-78 is apparent from at least two of the guidelines for the determination of unity of invention provided in the Annex B to the Administrative Instructions under the P.C.T. (the "Administrative Instructions"):

(1) Unity of invention is apparent from the dependency of claims 79-85, 87-92 and 100 from claim 1. The Administrative Instructions explain that "[i]f the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims" Administrative Instructions under the P.C.T. Annex B, para. (c)(i).

(2) Unity of invention is also apparent because claims 1-78 and claims 79-85, 87-92 and 100 are related as claims to a product, and claims to methods using the product. The Administrative Instructions explain that the standard for unity of invention under Rule 13.2 permits "in addition to an independent claim for a given product ... an independent claim for a use of the said product." Administrative Instructions under the P.C.T. Annex B, para. (c)(i).

(B) Even If Lack of Unity of Invention Were Established the Groups From Which Election is Being Required are Arbitrary and Improper

(1) The Restriction Requirement Does Not Consider Applicants' *Claimed* Invention

The MPEP emphasizes that in making a restriction requirement "it is the *claimed* subject matter that is considered". MPEP 806.01 (emphasis added).

The restriction requirement, however, does not appear to consider the definitions in the *claims* of the application, as is required for properly making a restriction requirement. It is not seen from where in the claims the Examiner has derived the various definitions used to define the claims. For example, Ar_1 in the claims is not limited to phenyl or pyrazole. Further, with regard to the applicants' elected group, Group V, the applicants do not see a definition in the claims where "A, B, and D form a 6-membered ring."

Since the restriction requirement is not based on the definition of the invention as set forth in the *claims*, as is required for a proper restriction requirement, the requirement being made is manifestly improper.

(2) The Restriction Requirement Abridges The Applicants Right To Claim The Generic Subject Matter Which The Applicants Regard As Their Invention

Dividing the claims as required in the restriction requirement would improperly require the claims to be limited to the genera defined by the Examiner in defining the Groups rather than those claimed by the applicants in the application. If the restriction requirement were maintained, the applicants would therefore be denied the right to claim the generic concept described in the application. This is improper because 35 U.S.C. § 112 makes clear that the claims should point out "the subject matter which *the applicant* regards as his invention".

The courts have made it clear that applicants have a right to claim their invention however they see fit so long as it complies with the second paragraph of 35 U.S.C. § 112. Indeed, the right of an applicant to claim an invention generically has been established for over a hundred years. *See Ex parte Eagle*, 1870 C.D. 137, 138 (Comm'r Dec. 1870). The courts have held that a restriction requirement of the type made in the present action would violate the applicants' right to claim an invention generically because "that claim would never be considered on its merits [and]...[t]he totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim." *In re Weber*, 580 F.2d 455, 458 (C.C.P.A. 1978).

The restriction requirement being made in the present application, if maintained, would violate the applicants' right to claim what they regard as their invention by requiring the claims to be rewritten in a manner where generic terms the applicants have used in describing their invention to have to be replaced by different terms having a different meaning. For example, the Office would have the applicants substitute the generic definition of Ar_1 as "aryl or heteroaryl each optionally substituted ..." by narrower definitions as *particular* aryl or heteroaryl rings, i.e. as phenyl or pyrazole, which are the only options provided for Ar_1 in the Examiner's groupings.

The right of the Office to insist upon restriction when an application claims more than one invention does not give the right for the Office rewrite the applicants' claims to an invention that has properly been described using *bona fide* generic terms. The fact that the claims might encompass more than one invention in the sense of dominating them is an insufficient reason for maintaining a restriction requirement where a generic claim encompasses more than one of the inventions. *See In re Weber*, 580 F.2d 455, 460 (C.C.P.A. 1978) (Rich J. concurring). That the compounds of Groups I-XIII are dominated by claim 1, therefore, does not detract from the fact that claim 1 nevertheless properly claims applicants' invention in generic terms.

(3) The Arbitrary Definitions of the Groups Would Deprive the Applicants of Their Right To Claim The Entirety of Their Invention

A proper restriction requirement should encompass and account for all elements of the original claims, without any voids or ambiguities, so that applicants' entire claimed invention may be examined eventually. An applicant has a right to have each claim examined on the merits in its entirety. *In re Weber*, 580 F.2d 455 (CCPA 1978). The totality of any fragmentary claims must necessarily be the equivalent of the original claim. *Id.* at 458. The applicant has a right to claim his invention as he chooses, and this statutory right takes priority over perceived administrative needs. *Id.* at 459.

MPEP 806.01 reminds examiners that "[i]n passing upon questions of ... restriction, it is the *claimed* subject matter that is considered and such claimed subject matter must be compared in order to determine the question of distinctness or independence." While it is unclear why the examiner has chosen only phenyl and pyrazole in the definitions of the various Groups, the choice does not appear to be based upon the definitions in the claims. Claim 1 defines Ar_1 as "aryl or heteroaryl..." and not "phenyl or pyrazole" – which appears to be a narrower definition not based on what is in the claims.

By splitting the compound claims in the manner proposed in the restriction requirement, the Office is creating artificial genera that are different from those claimed in the application. The invention claimed in claim 1 (for example) is the compound wherein defines Ar_1 as "aryl or

heteroaryl..." and not as "phenyl or pyrazole". If the applicants are to pursue subject matter of their invention according to the division proposed by the Examiner, they would be forced to divide and reformulate the subject matter into multiple claims that comply with the restriction and written description requirements by canceling various subject matter. As a result, the scope of the resulting fragments would not equal the originally claimed scope as required, and could potentially be marred with voids and ambiguities of inaccessible subject matter so that the applicants might have to forego rights to subject matter to which they would otherwise be entitled. Forced forfeiture of rights resulting from the contrived and artificial delineation of the compound claims as specified in the Office action merely due to administrative conveniences is clearly beyond the bounds of statutory authority as discussed in *In re Weber*, supra.

The Examiner's "catch all" Group (Group XIII) emphasizes, rather than cures, the arbitrary nature of the Groupings caused by the Examiner's failure (if any restriction requirement is justified) to base the restriction requirement on the claims. The Examiner clearly recognizes the deficiency arising from the arbitrary and artificial Group definitions in the restriction requirement arising from the failure to base the restriction requirement on the definitions in the claims. The formalistic solution creating Group XIII as a "catch all group" – which includes anything not within the arbitrary definitions of Groups I-XII – using set logic does not cure the deficiency in the restriction requirement brought about by the improper and arbitrary nature of the definitions of Groups I-XII.

(4) Even If a Lack of Unity of Invention Were Established, The Arbitrary Definitions of the Groups Would Limit Applicants' Invention More Than Could Conceivably Be Required To Restore Unity of Invention

Even if unity of invention is found to be lacking as to one or more claims, the Office is not thereby given "carte blanche" under the P.C.T. to divide applicants' claims as he sees fit because applicants have the "right to include in a single application ... those inventions which are so linked as to form a single general inventive concept", MPEP 1893.03(d). Therefore even if there is lack of unity of invention as to some of the claims, restriction is permissible only to the

extent necessary to restore unity of invention. The applicants are entitled to retain in the application all of the subject matter sharing unity of invention with the applicants' elected Group.

The Examiner has completely failed to show that each of the groups among which restriction is being required lacks unity with each of the other Groups. MPEP 1893.01(d) explicitly requires that when making a lack of unity of invention restriction requirement, the Examiner must not list the different groups of claims but must also "***explain why each group lacks unity with each other group*** (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group." The Examiner has completely failed to fulfill the latter requirement, and did not explain how each of the groups lack unity with every one of the other groups.

Here, the groups designated by the Examiner were completely arbitrary, and no showing was made that each group lacked unity with every other group. Focusing on the applicants' elected Group, even if the Office had been successful in showing lack of unity of invention, the Office does not explain why Ar_1 should be limited only to phenyl and any other aromatic groups within the definition of "aryl or heteroaryl" as claimed in claim 1, why X and Y should be limited to N rather than the definitions in claim 1, why the definitions of A, B, and D such that the ring containing them is a 6-membered ring, and why the definitions of the linker group –V–W– must be limited in order to restore unity of invention. The restriction requirement would even place arbitrary restrictions on peripheral substituents (for example, the definition of Group V limits R^4 to hydrogen and not alkyl). It is not seen how these arbitrary definitions can in any way conceivably be related to a requirement to maintain unity of invention. The Examiner has not shown how Group V lacks unity of invention with each of the other seventeen groups.

There is also no basis for the Office to require restriction between the compound and method of use claims from the compound claims, since claims to a product and method of its use share unity of invention under proper P.C.T. practice described above.

(C) Undue Burden

MPEP 803 explains that if the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though restriction might otherwise be proper. *See* MPEP 803.

The Office's contention that a search here of all the products and methods encompassed by the claims would unduly burdensome is not compelling. A search of the same scope as that which the Examiner asserts would be unduly burdensome and difficult to perform has *already been performed* by a proficient searching authority in the International Phase. As was pointed out above, the present application was filed as PCT Application PCT/US2004/001267 and preliminarily examined in the international phase by the European Patent Office. An International Preliminary Report on Patentability (IPRP) was issued on July 15, 2005. The International Searching Authority *performed a complete search* with respect to the claimed invention, noting no issues with regard to undue burden and raising no issues with regard to unity of invention. It is not seen how or why it would be unduly burdensome or difficult for the Examiner to perform a search of the same scope as one performed by the European Patent Office without raising any such issues in the International phase.

Further, in view of the substantial structural similarities shared by all compounds according to formula Ia, it would clearly not constitute an undue burden for the Office to search all of the claims together. For example, the substantial sub-structure identified above could serve as the basis for a computational search in the Chemical Abstracts database, and thus could readily be searched together by the Office.

(D) Incompleteness of the Restriction Requirement

MPEP 815 explains that "[w]hen making a restriction requirement every effort should be made to have the requirement complete." It is apparent from the Office Action, however, that the restriction requirement is not in fact complete because Groups I-XII clearly include less than all of the compounds within the scope of claim 1. It is respectfully submitted that the "catch-all" Group XIII is improper because it is not based on the claimed subject matter, though its inclusion

clearly acknowledges the incompleteness of the subject matter (as to the claimed compounds) included in Groups I-XII.

The restriction requirement is therefore also improper because it is incomplete.

(E) Lack of Clarity of the Restriction Requirement

The traversal is made on the ground that the restriction requirement lacks clarity. MPEP 814 explains that "[t]he examiner must provide a clear and detailed record of the restriction requirement to provide a clear demarcation between restricted inventions so that it can be determined whether inventions claimed in a continuing application are consonant with the restriction requirement and therefore subject to the prohibition against double patenting rejections under 35 U.S.C. 121." MPEP 814 (citing *Geneva Pharms. Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1381 (Fed. Cir. 2003).

The lack of clarity is in part due to the incompleteness of the restriction requirement and the fact that the Examiner's definitions of the Groups differ from those in the application. It is not possible to tell certain embodiments of the invention would fall within the scope of one of the elected Groups or be relegated to the "catch all" Group XVIII. For example, various of the Group definitions require "optionally fused phenyl ring." However, when a ring is fused, more than one ring is present. This definition is confusing. For example, applicants assume that the definition is intended to include naphthyl, for example, but is it also intended to include quinoline (phenyl fused with pyridyl), indole (phenyl fused with pyrrole), benzofuran (phenyl fused with furan) and the like? If the latter heterocyclic ring systems are intended to be included, the applicants are even more confused as to why other heterocycles (e.g. the non-benzo-fused ones, such as pyridyl) must be excluded for any reason related to maintaining unity of invention.

The restriction requirement also lacks clarity because the definitions of the Groups are inconsistent with the definitions of the corresponding claims. Each of the Groups is I-XIII is identified as including claims 1-78. However, the definitions of the claims are not consistent with including each of the claims in each of the Groups. Group V, for example, is defined as follows:

> **Group V**. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 6-membered ring; V is alkyl or absent; W is NH; and Ar1 is an optionally fused phenyl ring, according to Claims 1-78.

The definition of claim 4, however, is inconsistent with this definition (because claim 4 requires W as NR^4 and R^4 as CH_3 or CH_2CH_3, whereas the above definition would clearly require R^4 as hydrogen. Thus, the definitions are unclear and contradictory. Since Group V is said to include all of Claims 1-78 (presumably including claim 4), it is not clear what compounds according to claim 4 are included in Group V. Is it the definition of W in Group V which is incorrect? (Perhaps it was intended to be NR^4). Or is it the designation of the claims encompassed by Group V which is incorrect? (Perhaps it was not intended to include Claim 4). The definition of Group V, therefore, appears to be irresolvably ambiguous. Similar ambiguities exist for each of the other Groups I-XIII.

The restriction requirement is therefore also improper because it is unclear.

(F) Linking Claims

Reconsideration of the restriction requirement is also requested because linking claims are present in the application. For example, claim 1 and claim 78 are linking claims linking the allegedly distinct inventions encompassed by Groups I-XIII. As described in MPEP 809, even though an application might encompass claims to two or more properly divisible inventions such that a requirement to restrict the claims of the application to one would be proper, a linking claim, if allowable, can require rejoinder of the claims to the allegedly distinct inventions. One situation where this arises is where there are genus claims linking species claims. Claims 1 and 78 are genus claims linking all of the species of Groups I-XIII, because both claims encompass all of Groups I-XIII. The MPEP makes clear that "the linking claims must be examined with, and thus are considered part of, the invention elected." While it is recognized that the MPEP might provide for a provisional restriction requirement to be made in such a situation (under the procedures set forth in MPEP 809.03), it is not clear that this is what is contemplated by the examiner here because the Office Action does not indicate that the restriction requirement as to

the linked inventions is to be withdrawn upon an indication of the allowability of the linking claim(s). See MPEP 809.03.

(F) Conclusion

Based on the foregoing, it is respectfully submitted that the requirement for unity of invention is satisfied because the common features of the compounds according to formula Ia as defined in claim 1 constitute a special technical feature linking the claims. Since a restriction requirement made in an National Phase Application filed under 35 U.S.C. § 371 is improper when the requirements of unity of invention is satisfied, it is respectfully submitted that the restriction requirement made in the Office Action mailed July 3, 2008 is improper and should be withdrawn. The applicants respectfully request that the restriction requirement made be withdrawn and that the Office proceed to the examination of the full scope of the applicants' claims.

Please apply any charges or credits to Deposit Account No. 06-1050 referencing Attorney Docket No. 20750-0007US1.

Respectfully submitted,

Date: 12/19/2008

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